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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/038,110 | 11/09/2001 | Kurt Polzhofer | 0288-025P/JAB | 5375 |

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| EXAMINER | |
|---|---|
| STULTZ, JESSICA T | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 2873 | |

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/038,110 | POLZHOFER ET AL. | |
| | Examiner | Art Unit | |
| | Jessica T Stultz | 2873 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *8/7/2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *22-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25,27 and 31-43* is/are rejected.

7)☒ Claim(s) *26,28-30 and 44-47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-25, 27, and 31-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al in view of Friends et al US patent No. 4,663,409.

Regarding claim 22 and 24, Watanabe et al discloses a hydrogel contact lens having a base material comprising copolymerized monomers, which are modified with betaine (Column 20, line 29-Column 21, line 47), but does not specifically disclose that the monomers are modified with at least one amino acid. However, Friends et al teaches that amino acids, specifically either glycine, proline, glutamine, alanine, arganine, asparagine, lysine, leucine, serine or isoleucine (Column 3, lines 21-33) are commonly used in polymeric compositions, such as being cross-linked with hydroxyethyl methacrylate (Column 2, lines 5-33), which can be used to make contact lenses, to increase the water content and oxygen permeability without significantly changing other properties of the polymer (Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made for the hydrogel contact lens of Watanabe et al to further include that the base monomers be modified with at least one amino acid since Friends et al teaches that amino acids are commonly used in polymeric compositions, such as being cross-linked with hydroxyethyl methacrylate, which can

be used to make contact lenses, to increase the water content and oxygen permeability without significantly changing other properties of the polymer.

Regarding claim 23, it would have been obvious from Watanabe et al that the at least one amino acid is an amino acid occurring in the natural collagen of the cornea, since it is well known in the art of collagen that amino acids are the building blocks of collagen.

Regarding claims 25 and 27, Watanabe et al and Friends et al disclose and teach of the hydrogel contact lens as disclosed above and Friends further teaches the monomer modified by the amino acid is methacryloyl amino acid (Column 8 line 64-Column 9, line 13) and that the percentage of amino acid in the modified polymer is 0.5% to 25% by weight (Column 16, lines 30-32). Therefore it would have been obvious to one having ordinary skill in that art at the time the invention was made for the hydrogel contact lens of Watanabe et al to further include the modified monomer as methacryloyl amino acid and the percentage of amino acid in the modified polymer be 0.5% to 25% by weight since Friends teaches that the monomer modified by the amino acid is methacryloyl amino acid and that the percentage of amino acid in the modified polymer is 0.5% to 25% by weight.

Regarding claim 31, Watanabe et al further discloses that the base material include any of the following: hydroxyethyl methacrylate, hydroxypropyl methacrylate, vinylpyrrolidone, or other acrylaminde derivatives (Column 9, lines 30-44).

Regarding claim 32, Watanabe et al further discloses that the base of the contact lens includes dimethylacrylamide (Column 20, lines 29-Column 21, line 3).

Regarding claim 33, Watanabe et al further discloses that the base material constitutes 53% to 99% by weight of the polymer (Column 8, lines 32-39).

Regarding claim 34, Watanabe et al further discloses that the refractive index of the contact lens is 1.22 to 1.51 (Columns 30-31, Tables 1 and 2, Examples 1-8).

Regarding claim 35, Watanabe et al further discloses that the contact lens, in a swollen state contains more than 50% by weight of water (Column 30-31, Tables 1 and 2, Examples 2-5, and 8).

Regarding claim 36, Watanabe et al further discloses that the contact lens, in a swollen state contains 55% to 60% of water (Column 31, Table 1, Example 5).

Regarding claim 37, Watanabe et al further discloses that the contact lens has an oxygen permeability Dk value of $>8 \times 10^{-11}$ (Columns 30-31, Tables 1-3, Examples 1-8).

Regarding claims 38-40, Watanabe et al discloses a method of preparing a polymer material for a hydrogel contact lens comprising the steps of mixing at least one methacrylate monomer, and at least one monomer based on betaine (Column 20, line 29-Column 21, line 47) by using a cross-linking agent (Column 11, line 46-Column 12, line 13), but does not specifically disclose the step of mixing in at least one monomer based on an amino acid and that the monomers are polymerized with a starter. However, Friends et al discloses that amino acids are commonly used in polymeric compositions, such as being cross-linked with hydroxyethyl methacrylate (Column 2, lines 5-33 and Column 5, lines 4-20), which can be used as contact lenses, to increase the water content and oxygen permeability without significantly changing other properties of the polymer and that the polymerization is started by a free radical initiator, specifically peroxides or azo compounds (Column 5, lines 4-20), to cast the polymer into the desired shapes (Abstract). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the hydrogel contact lens of Watanabe et al to be

made of at least one monomer based on an amino acid and that the monomers would be polymerized with a starter since Friends et al discloses that amino acids are commonly used in polymeric compositions, such as being cross-linked with hydroxyethyl methacrylate, such as contact lenses to increase the water content and oxygen permeability without significantly changing other properties of the polymer and that the polymerization is started by a free radical initiator to cast the polymer into the desired shapes.

Regarding claim 41, Watanabe et al further discloses that the cross-linking agent is added in an amount of 0.01% to 3% by weight (Column 12, lines 8-13).

Regarding claim 42, Watanabe et al further discloses that the contact lens is polymerized individually as a cast lens with a polymerization time of less than one hour (Column 18, lines 43-49).

Regarding claim 43, Watanabe et al further discloses that the reaction starter is added in an amount of 0.2% to 0.5% by weight (Column 24, lines 14-26).

***Allowable Subject Matter***

Claims 26, 28-30, and 44-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: none of the prior art either alone or in combination disclose or teach of the claimed combination of limitations to warrant a rejection under 35 USC 102 or 103.

Specifically in reference to claim 26, none of the prior art either alone or in combination disclose or teach of a hydrogel contact lens as disclosed above specifically wherein the monomer

modified with at least one amino acid is copolymerized with a main chain or a side chain of the base material of the contact lens or both.

Specifically in reference to claims 28-30, none of the prior art either alone or in combination disclose or teach of a hydrogel contact lens as disclosed above specifically wherein the betaine is at least one of a sulfobetaine and a carboxybetaine chosen to form a block-free copolymer with the base material.

Specifically in reference to claims 44-45, none of the prior art either alone or in combination disclose or teach of a method of making a polymer for a hydrogel contact lens as disclosed above specifically wherein the material initially is polymerized into a block-shape for approximately 1 to 3 days at a controlled temperature and the individual contact lenses are then machined out of the block material.

Specifically in reference to claims 46, none of the prior art either alone or in combination disclose or teach of a method of making a polymer for a hydrogel contact lens as disclosed above specifically wherein the up to 20% glycerin is added for the polymerization step.

Specifically in reference to claims 47, none of the prior art either alone or in combination disclose or teach of a method of making a polymer for a hydrogel contact lens as disclosed above wherein the percentage of monomers base on amino acids is 0.5% to 25% by weight, the percentage of methacrylate monomers is 99% to 53% by weight, and specifically wherein the percentage of monomers based on betaine is 0.5% to 22% by weight.

***Response to Arguments***

Applicant's arguments filed August 7, 2003 have been fully considered but they are not persuasive. Specifically the applicant argues that the combination of references Watanabe et al

'594 and Friends '407 is based on hindsight by the disclosure of the present application. However, the motivation to combine these references comes from Friends '407 (Abstract) which would enhance the properties of the contact lens disclosed in Watanabe et al '594.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica T Stultz whose telephone number is (703) 305-6106. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Epps can be reached on 703-308-4883. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7722 for regular communications and 703-308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.

Jessica Stultz
September 11, 2003

JORDAN SCHWARTZ
PRIMARY EXAMINER